

Art Unit: 1646

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Joseph A. Hynds on 3/15/2010.

#### Double Patenting Rejection:

Provisional rejection of claims 1 and 3-5 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-5 of co-pending Application No. 10/581,597, as set forth on pages 5-6 of the office action mailed on 2/24/2009, is withdrawn in view of the allowability of the instant claims, and an interview with Mr. Joseph A. Hynds on 3/30/2010, in which he stated that a terminal disclaimer will be submitted in the '597 application.

#### In the claims:

Please amend claim 1 to read:

"A process for purifying human interferon beta from a recombinant human interferon beta-containing culture comprising performing affinity chromatography and reversed-phase high-performance liquid chromatography (RP-HPLC), wherein the affinity chromatography comprises:

adsorbing the interferon beta-containing culture to an equilibrated affinity chromatography column, followed by washing with an equilibration buffer solution;

followed by washing the column with a first washing buffer solution A of pH 6.5-7.5 containing 30-60 wt% of propylene glycol;

followed by washing the column with a second washing buffer solution C of pH 6.5-7.5 containing 1-2M NaCl;

followed by washing the column with a third washing buffer solution B of pH 6.5-7.5 containing 10-30 wt% propylene glycol and 1-2M NaCl; and then eluting a human interferon beta-containing fraction with a buffer solution of pH 6.5-7.5 containing 40-60 wt% propylene glycol and 1-2M NaCl."

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2. Please amend claim 4 to read:

“The process of claim 1, wherein a solution obtained by the affinity chromatography is, before the RP-HPLC, is subjected to diafiltration with an ultrafiltration membrane with a molecular weight cut-off of 10,000 daltons.”

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571)272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Robert Landsman/  
Primary Examiner, Art Unit 1647